REMARKS

Claim Amendments

Claims 50-52 and 55-62 are currently pending in this application. Claim 61 stands withdrawn. Claims 50, 56 and 62 have been amended herein. Support for the amended claim 50 is found throughout the specification as originally filed, *inter alia*, at page 5, lines 2-4; page 8, lines 14-17; page 12, line 8 – page 13, line 7 and page 14, lines 11-15. Support for the amended claim 62 is found throughout the specification as originally filed, *inter alia*, at page 4, line 7. Accordingly, Applicants assert that no new matter is introduced into the specification through entry of the present claim amendments. Upon entry of this amendment, claims 50-52 and 55-62 will be pending. Applicants respectfully request entry of the amendment and reconsideration of the pending claims.

Reply to Rejection Under 35 U.S.C. § 112, ¶ 1, Enablement

Claims 50-52, 55-60 and 62 were rejected under 35 U.S.C. § 112, ¶ 1 as allegedly failing to comply with the enablement requirement of 35 U.S.C. § 112, ¶ 1.

Applicants respectfully disagree and traverse this rejection.

The Final Action, on page 4, states that the claimed invention is directed to the treatment of diseases, rather than modulation of immune responses. The Examiner states that "the specification has provided and demonstrated a sufficient enabling disclosure for the modulation of the immune system." (Final Action, page 4, lines 3-5). Applicants submit that the specification offers guidance to those skilled in the art to practice the claimed process for modulating an immune response in a mammalian subject comprising administering to said subject an effective amount of a mammalian metabolite so as to modulate or change at least one component in the immune system of said subject, wherein the mammalian metabolite is a glycolipid, and wherein the immune response is part of the pathogenesis of a disease. The specification, as filed, provides guidance to one of skill in the art for modulating at least one component in the immune system by

administering a mammalian metabolite, as exemplified by activation of the NKT cell population, a particular component of the immune system. *See, e.g.,* page 13, line 23 – page 14, line 5. Applicants further submit that the specification, as filed, provides one of skill in the art teachings as to types of immune parameter or marker to gauge whether a substance would be useful for modulating an immune response wherein the immune response is part of the pathogenesis of a disease, *e.g.,* T-cells, IFN-gamma, IL-4, IL-10 and peripheral NKT lymphocytes. Applicants submit that the specification provides evidence that specific immune parameters are modulated in response to a metabolite, such as a glycolipid. For example, Figures 1-6 illustrate the results of assays leading to T-cell proliferation and changes in IFNγ serum levels, IL-4 serum levels, IL-10 serum levels and peripheral NKT lymphocytes. Additionally, the specification provides as follows:

> These assays and figures demonstrate that the presence of an increased level of a metabolite has led to significant changes in the immune profile of these subjects. Surprisingly, when this condition was accompanied by another immune system challenge (HCV infection), there was significant impact on the immune profile of the HCV+ subjects compared to the subjects that lacked elevation of the metabolite.

See Specification at page 12, first full paragraph.

It is well established under 35 U.S.C. §112 ¶ 1, that, "[t]he test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is *undue*." MPEP 2164.01 (citing *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976) (Emphasis added). Therefore, the specification provides sufficient guidance enabling one skilled in the art to administer a glycolipid for the purposes of modulating at least one immune parameter, such as T-cells, IFN-gamma, IL-4, IL-10 and peripheral NKT lymphocytes, for example. Applicants further submit that the working examples clearly set forth a protocol for testing an agent's ability to modulate at least one component of the immune system, which amounts to adequate guidance to test a glycolipid of interest. The specification also teaches one of skill in the art that another parameter, which may be modulated and assayed, is the intracellular or extracellular serum level of the mammalian metabolite itself. *See, e.g.,* page 4, lines 12-

15 and page 14, line 24 – page 15, line 5 and page 12, lines 15 – page 13, line 3. The at least one change in an immune component of the subject may provide either enhanced immune response or reduced immune response or both. *See* page 12, lines 15-18. Accordingly, one of skill in the art is adequately guided as to associating the presence or level of an immune marker or parameter with the modulating an immune response. Given the level of skill in the art, the breadth of the claims, the presence of examples, the amount of direction or guidance presented and the quantity of experimentation necessary, the presently pending claims are fully enabled by the specification as filed.

For the reasons above, Applicants respectfully submit that the claims as currently amended are enabled by the instant specification, and as such, a skilled artisan is sufficiently guided to make and use the claimed invention commensurate with the scope of the presently amended claims without undue experimentation. Applicants respectfully request reconsideration and withdrawal of this rejection.

Reply to Double Patenting Rejection

Claim 55 has been provisionally rejected again on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 106 of copending application no. 10/675,980. At page 10, lines 4-5 of the Final Action, the Examiner states that "until the rejection is properly addressed, the rejection is maintained." Applicants respectfully submit that the rejection has been addressed above. Applicants also respectfully submit that as this is a provisional double patenting rejection, no action is required by Applicants until such time that the subject matter in copending application no. 10/675,980 is allowed. For the convenience of the Examiner, Applicants cite the relevant excerpt from M.P.E.P. 1504.06 Double Patenting, which states as follows:

> If a provisional double patenting rejection (of any type) is the only rejection remaining in two conflicting applications, the examiner should withdraw that rejection in one of the applications (e.g., the application with the earlier filing date) and permit the application to issue as a patent. The examiner should maintain the provisional double patenting rejection in the other application which rejection will be converted into a double patenting rejection when the first application issues as a patent. If more than two applications conflict with each

other and one is allowed, the remaining applications should be cross rejected against the others as well as the allowed application.

In view of the foregoing amendments and response, Applicants respectfully request the withdrawal of this and all other outstanding rejections.

CONCLUSION

Early notification of a favorable consideration is respectfully requested. The Examiner is respectfully requested to contact the undersigned by telephone at the below listed telephone number, in order to expedite resolution of any issues and to expedite passage of the present application to issue, if any comments, questions, or suggestions arise in connection with the present application.

Respectfully submitted,

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